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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/613,736 | 07/03/2003 | Arthur M. Krieg | C1037.70044US00 | 4723 |

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| EXAMINER | |
|---|---|
| ARCHIE, NINA | |

| ART UNIT | PAPER NUMBER |
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| 1645 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/613,736 | KRIEG, ARTHUR M. | |
| | Examiner | Art Unit | |
| | Nina A. Archie | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-21,23,28-33,44,46-58,64-66,71-74,77-81,84,85,89,90,95,96,98 and 99.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-21,23,28-33,44,46-58,64-66,71-74,77-81,84,85,89,90,95,96,98 and 99.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 23, 28-33, and 44 drawn to a composition, classified in class 536, subclass 25.3.

II. Claims 46-58, 64-66, 71-74, 77-81, 84-85, 89, 90, 95, 96, and 98 are drawn to a method for stimulating an immune response in a subject in need thereof and a method for inducing an innate immune response, classified in class 424, subclass 9.341.

III. Claim 99, drawn to a method for identifying an immunostimulatory nucleic acid, classified in class 424, subclass 9.341.

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of Invention II, which is a method for stimulating an immune response in a subject in need thereof, does not have to use the product of Invention I comprising a composition. For example an antigen can be used in the drawn to a method for stimulating an immune response in a subject in need thereof and a method for inducing an innate immune response.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of Invention III, which is

a method for identifying an immunostimulatory nucleic acid, does not have to use the product of Invention I comprising a composition. For example an antigen can be used in the method for identifying an immunostimulatory nucleic acid.

4. Groups II and III are drawn to independent and distinct methods, which differ in the method objectives, method steps, in the reagents used, and have different final outcomes. Group II, which is drawn to a method for stimulating an immune response in a subject in need thereof and a method for inducing an innate immune response, Group III, which is drawn to a method for identifying an immunostimulatory nucleic acid. Each group differs in the method objectives, method steps, in the reagents used, and have different final outcomes.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

**Election of Species**

If the Applicant elects Invention I, the Applicant is required to elect specific combination for Species 1, Species 2, and Species 3 for Invention I.

Species 1-Antigen;
A) microbial antigen
B) cancer antigen
C) allergen
D) peptide antigen

If A is selected, Applicant is respectfully required to further elect a microbial antigen

A) bacterial antigen

B) viral antigen

C) fungal antigen

D) parasitic antigen

Species 2- Therapeutic Agent;

A) anti-microbial agent

B) anti-cancer agent

C) allergy/asthma medicament

If A is selected, Applicant is respectfully required to further elect an anti-microbial agent

A) anti-bacterial agent

B) anti-viral agent

C) anti-fungal agent

D) anti-parasite agent

If B is selected, Applicant is respectfully required to further elect an anti-cancer agent

A) chemotherapeutic agent

B) cancer vaccine

C) immunotherapeutic agent

If C is selected, Applicant is respectfully required to further elect an allergy/asthma medicament

A) PDE-4 inhibitor

B) bronchodilator/beta-2 agonist

C) K+ channel opener

D) VLA-4 antagonist

E) neurokin antagonist

F) TXA2 synthesis inhibitor

G) xanthanine, arachidonic acid antagonist

H) 5 lipoxygenase inhibitor

I) thromboxin A2 receptor antagonist

J) thromboxane A2 antagonist

K) inhibitor of 5-1ipox activation protein

L) protease inhibitor.

Species 3- Routes of Administration;

A) local administration

B) parenteral administration

If the Applicant elects Invention II, the Applicant is required to elect specific combination for Species 1, Species 2, Species 3, Species 4, Species 5, and Species 6 for Invention II.

Species 1-Antigen;

A) microbial antigen

B) cancer antigen

C) allergen

D) peptide antigen

E) self antigen

If A is selected, Applicant is respectfully required to further elect a microbial antigen

A) bacterial antigen

B) viral antigen

C) fungal antigen

D) parasitic antigen

If A is selected, Applicant is respectfully required to further elect an antigen derived from a microorganism

A) herpesviridae
B) retroviridae
C) orthomyroviridae
D) toxoplasma
E) haemophilus
F) campylobacter
G) clostridium
H) E.coli
I) staphylococcus.

Species 2- Therapeutic Agent/Microbial agent;

A) anti-bacterial agent
B) anti-viral agent
C) anti-fungal agent
D) anti-parasite agent

Species 3-Risk;
A) Infection
B) Allergy
C) Asthma
D) Cancer.

If A is selected, Applicant is respectfully required to further elect an infection

A) bacterial infection

B) viral infection

C) fungal infection

D) parasite infection

If B is selected from viral infection species, Applicant is respectfully required to further elect a viral infection

A) (HIV-1)

B) (HIV-2)

C) Human T lymphotropic virus type I (HTLV-I)

D) Human T lymphotrophic virus type II (HTLV-II)

E) Herpes simplex virus type I (HSV-1)

F) Herpes simplex virus type 2 (HSV-2)

G) Human papilloma virus (multiple types),

H) Hepatitis A virus

I) Hepatitis B virus

J) Hepatitis C virus

K) Hepatitis D virus

L) Epstein-Barr virus (EBV)

M) Cytomegalovirus

N) Molluscum contagiosum virus.

If D is selected from cancer species, Applicant is respectfully required to further elect a cancer

A) biliary tract cancer

B) bone cancer

C) brain and CNS cancer

D) breast cancer

E) cervical cancer

F) choriocarcinoma

G) colon cancer

H) connective tissue cancer

I) endometrial cancer

J) esophageal cancer

K) eye cancer

L) gastric cancer

M) Hodgkin's lymphoma

N) intraepithelial neoplasms

O) larynx cancer

P) lymphomas

Q) liver cancer

R) lung cancer (e.g. small cell and non-small cell)

S) melanoma

T) neuroblastomas

U) oral cavity cancer

V) ovarian cancer

W) pancreas cancer

X) prostate cancer

Y) rectal cancer

Z) sarcomas

AA) skin cancer

BB) testicular cancer

CC) thyroid cancer

DD) renal cancer

Species 4-Mucosal Surface;

A) oral

B) nasal

C) rectal

D) vaginal

E) ocular surface

Species 5-Subject;

A) dog

B) cat

C) horse

D) cow

E) pig

F) sheep

G) goat

H) chicken

I) monkey

J) fish

Species 6- Routes of Administration;

A) orally

B) locally

C) parenterally

This application contains claims directed to the following patentably distinct species of antigens for Species 1, species of therapeutic agents for Species 2, and species of routes of administration for Species 3 for Invention I and species of antigens for Species 1, species of therapeutic/microbial agents for Species 2, species of risk for Species 3, species of mucosal surfaces for Species 4, species of subjects for Species 5, and species of routes of administrations for Species 6 for Invention II. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a specific combination for Invention I and a specific combination for Invention II for the prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. To clarify, Applicant should elect a specific combination for Species 1-3 for Invention I and a specific combination for Species 1-6 for Invention II. Currently, claims 1-3, 6-7, 9-11, 17-21, 23, 28-29, 32-33, and 44 (Invention I), claims 46, 58, 64, 71-74, 80-81, 85, 89, 96, and 98 (Invention II), and claim 99 (Invention III) are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Notice of Possible Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER